IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

CIVIL ACTION
No. 2:06-cv-00027-NBF

Judge Fischer

5 UNLABELED BOXES, more or less, of an article of food, each box containing various quantities of 100 tablet bottles, labeled in part:

(Bottle)

"***Lipodrene*** Dietary Supplement***100 ct. ***25 mg ephedrine group alkaloids***
Manufactured for: Hi-Tech Pharmaceuticals, Inc.***
Norcross, GA***
05121004EXP09/08***,"

Defendant.

and, HI-TECH PHARMACEUTICALS, INC.

v.

ANDREW C. VON ESCHENBACH, M.D. Commissioner of the U.S. Food and Drug Administration; FOOD AND DRUG ADMINISTRATION; MICHAEL O. LEAVITT, Secretary of the Department of Health and Human Services; DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendants.

MEMORANDUM OPINION

I. INTRODUCTION

The above-captioned matter is presently before the Court upon submission of the following by the parties:

1) The United States of America (hereafter "Government") and Third Party Defendants, Andrew C. von Eschenbach (hereafter "von Eshenbach"), M.D., Acting Commissioner of the United States Food and Drug Administration (hereafter "FDA"), Michael O. Leavitt, Secretary of the Department of Health and Human Services (hereafter "DHHS"), and DHHS's (hereafter, collectively, the "Government"), motion for summary judgment and related briefs, statement of facts, and appendix (Docket Nos. 34, 35, 36, and 37);

2) Third-Party Plaintiff and Claimant Hi-Tech Pharmaceuticals, Inc.'s (hereafter "Hi-Tech") response to the Government's motion for summary judgment and related brief (Docket Nos. 47 and 44);

3) Hi-Tech's motion for summary judgment and related briefs (Docket Nos. 45 and 46);

4) The Government's reply in opposition to Hi-Tech's motion for summary judgment and in support of the Government's motion for summary judgment, and documents in support thereof (Docket Nos. 52, 53, 54, and 55);

5) Hi-Tech's reply memorandum in support of its motion for summary judgment (Docket No. 56);

6) Hi-Tech's notice to the Court regarding the effect of the *Nutraceutical* decision on the instant case (Docket No. 59); and

7) The Government's notice to the Court advising of any changes to case law concerning issues in the pending summary judgment motions (Docket No. 60).

This case arises out of the seizure and requested condemnation of the above-captioned "five unlabeled boxes" by the Government and Hi-Tech's opposition to same based upon, *inter alia*, statutory challenges to the Government's rule-making process in regulating and banning the sale of ephedrine alkaloid dietary supplements (hereinafter "EDS"), such as those the Government seized, and the application of the Government's rules to said supplements. Upon consideration of the parties' motions for summary judgment and related documents, and the well-reasoned and persuasive decisions in the cases of *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006), *cert. denied*, 2007 U.S. LEXIS 5176 (holding that the FDA properly conducted a risk benefit analysis, and that the FDA's determination that there is no dosage level of ephedrine dietary supplements that was acceptable was not arbitrary and capricious); and *Hi-Tech Pharm., Inc., v. Crawford*, Nos. 1:05-cv-02083-GET and 1:06-cv-00406-GET, 2007 WL 2345248 (N.D. Ga. Aug. 15, 2007)[1] (finding, *inter alia*, that the FDA established by a preponderance of the evidence that any dosage of EDS presents a significant or unreasonable risk of illness or injury, and therefore is properly considered "adulterated" under the Dietary Supplement Health Education Act), and *NVE Inc. v. HHS*, 436 F.3d 182 (3d Cir. 2006) (holding that FDA's factual determinations and legal conclusions are entitled to deference in a case involving a challenge by the maker of ephedrine alkaloid dietary supplements to the FDA's regulation banning such supplements), it is the decision of this Court that summary

[1] On October 9, 2007, the Government notified this Court that Hi-Tech has appealed the judgment and order of the United States District Court for the Northern District of Georgia in *Hi-Tech Pharm., Inc., v. Crawford, et. al.*, Nos. 1:05-c-02083-GET and 1:06-cv-00406-GET, 2007 WL 2345248 (N.D. Ga. Aug. 15, 2007) to the Court of Appeals for the Eleventh Circuit. (See Docket No. 62).

judgment shall be GRANTED in favor of the Government, and summary judgment shall be DENIED to Hi-Tech, for the reasons contained within this opinion.

II. LEGAL STANDARD - MOTION FOR SUMMARY JUDGMENT

Summary judgment under Federal Rule of Civil Procedure 56(c) is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Woodside v. Sch. Dist. of Phila. Bd. of Educ.*, 248 F.3d 129, 130 (3d Cir. 2001) (quoting *Foehl v. United States*, 238 F.3d 474, 477 (3d Cir. 2001)). In deciding a summary judgment motion, the court must "view the evidence ... through the prism of the substantive evidentiary burden" to determine "whether a jury could reasonably find either that the plaintiff proved his case by the quality and quantity of the evidence required by the governing law or that he did not." *Anderson v. CONRAIL*, 297 F.3d 242, 247 (3d Cir. 2002) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986)).

When the non-moving party will bear the burden of proof at trial, the moving party's burden can be "discharged by 'showing' – that is, pointing out to the District Court – that there is an absence of evidence to support the non-moving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party has carried this burden, the burden shifts to the non-moving party who cannot rest on the allegations of the pleadings and must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co.*, 998 F.2d 1224, 1230 (3d Cir. 1993). Thus, the non-moving party must go beyond the pleadings and present "specific facts showing that there is a genuine issue for

trial," Fed. R.Civ.P. 56(e), and cannot rely on unsupported assertions, conclusory allegations, or mere suspicions in attempting to survive a summary judgment motion. *Williams v. Borough of West Chester*, 891 F.2d 458, 460 (3d Cir. 1989) (citing *Celotex*, 477 U.S. at 325). The non-moving party must respond "by pointing to sufficient cognizable evidence to create material issues of fact concerning every element as to which the non-moving party will bear the burden of proof at trial." *Simpson v. Kay Jewelers*, 142 F.3d 639, 643 n.3 (3d Cir. 1998) (quoting *Fuentes v. Perskie*, 32 F.3d 759, 762 n.1 (3d Cir. 1994)).

The Court also notes that "[i]n considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. at 255; *see also Marino v. Ind. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004.); and *Doe v. County of Centre*, 242 F.3d 437, 446 (3d Cir. 2001).

Finally, the Court notes that Hi-Tech failed to provide a concise statement of material facts in response to the Government's Concise Statement of Material Facts Not in Dispute (Docket No. 36) in accordance with LR 56.1(C)(1), and consequently, the facts set forth in the concise statement of material facts submitted by the Government are deemed to be admitted by Hi-Tech for the purpose of the instant motion, in accordance with LR 56.1(E), and are the facts the Court finds persuasive.[2] *See Benko v. Portage Area School Dist.*, No. Civ. A. 03-233J, 2006 WL 1698317 (W.D. Pa. 2006); *Smith v. Burrows Corp.*, No. Civ. A. 00-1972, 2005 WL 2106594 (W.D. Pa. 2006); *Loving v. Borough of East McKeesport*, No. 2:02CV1727, 2005 WL 3560661

[2] The Court notes that Plaintiff failed to file, or even request leave to file, a responsive statement of facts as set forth in LR 56.1. *Ferace v. Hawley*, No. 05-1259, 2007 U.S. Dist. LEXIS 71437, at *2 n.1 (W.D. Pa. Sept. 26, 2007).

(W.D. Pa. 2005); *Ferace v. Hawley*, No. 05-1259, 2007 U.S. Dist. LEXIS 71437, at * 2 (W.D. Pa. Sept. 26, 2007).

III. FACTS

In light of the foregoing standard, the Court finds the following facts solely for the purpose of resolving these motions for summary judgment.

A. The FDA's Final Rule

On February 11, 2004, the FDA published the "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk" (hereafter "the Final Rule"), codified at 21 C.F.R. §119.1. (Docket No. 36, at ¶1); *see* 69 Fed. Reg. 6788 (Feb. 11, 2004). The Final Rule became effective on April 12, 2004, (Docket No. 36, at ¶4); *see* 69 Fed. Reg. at 6788, and was enacted under the Dietary Supplement Health Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994), amending the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399, and the FDA's general authority to issue regulations for the efficient enforcement of the Act, 21 U.S.C. § 371(a). (Docket No. 36, at ¶2); *see* 69 Fed. Reg. at 6794, 6796.

In the Final Rule, the FDA declared that dietary supplements containing ephedrine alkaloids "present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use." (Docket No. 36, at ¶3); 69 Fed Reg. at 6788. The Final Rule bans the sale and distribution of all EDS. (Docket No. 36, at ¶5); *see* 69 Fed. Reg. at 6793.[3]

[3] The process by which the Final Rule came to fruition is outlined in the case of *Hi-Tech*, 2007 WL 2345248. (Docket No. 61); *see also NVE*, 436 F.3d 182.

B. Background on Hi-Tech and its Product, Lipodrene

Hi-Tech manufactures, produces, markets, distributes, and sells in interstate commerce EDS products, including Lipodrene. (Docket No. 36, at ¶6). The seized articles, *i.e.*, the "five unlabeled boxes," are comprised of Lipodrene dietary supplements, (Docket No. 36, at ¶8), which consist in whole or in part of ingredients shipped in interstate commerce from outside of Pennsylvania.[4] (Docket No. 36, at ¶7). Hi-Tech's Lipodrene is labeled as containing 25 milligrams ("mg") "ephedrine group alkaloids"[5] per tablet. (*See* Docket No. 36, at ¶9). Hi-Tech's Lipodrene label recommends a dose of 50 mg ephedrine alkaloids (2 tablets) per day, and lists a maximum recommended dosage of 100 mg ephedrine per day. (Docket No. 36, at ¶ 10).

C. Seizure of the "Five Unlabled Boxes" and Procedural History of the Case

The Government published a "proof of publication of notice" that on January 12, 2006, the United States Marshall's Service seized, via a warrant, five unlabeled boxes, more or less, of an article of food (hereafter the "Defendant Articles"), as described in the caption. (Docket No. 5). The Defendant Articles were seized from ATF Fitness Products, Inc., located in Oakmont, Pennsylvania, and consisted in whole or part of ingredients that were shipped in interstate commerce from outside of Pennsylvania. (Docket No. 5); (Docket No.1, at ¶ 4). More specifically, the Defendant Articles contained various quantities of 100 tablet bottles of

[4] Hi-Tech is a corporation organized under the laws of the State of Georgia and has its principal place of business in Norcross, Georgia. (Docket No. 4, at ¶ 5);(Docket No. 3). Hi-Tech has admitted in its Answer, "upon information and belief" that the "five unlabeled boxes", in which it claimed an ownership interest, (Docket No. 3), consist in whole or part of ingredients that were shipped in interstate commerce from outside the state of Pennsylvania. (Docket No. 4, at ¶ 5).

[5] The FDA Final Rule describes ephedrine alkaloids as "chemical stimulants that occur naturally in some botanicals but which can be synthetically derived." 69 Fed. Reg. at 6789. Ephedrine alkaloids are used as ingredients in dietary supplements, and have been labeled and used primarily to achieve weight loss, enhance athletic performance, and boost energy. *Id.*

"Lipodrene," the bottle labels indicating that the product was a "dietary supplement" of "25 mg ephedrine group alkaloids" manufactured for Hi-Tech Pharmaceuticals. (Docket No.1 at ¶ 4); (Docket No. 5).

On January 19, 2006, the Government filed a "Complaint for Forfeiture," which requested seizure and condemnation of the Defendant Articles in accordance with the Federal Food, Drug and Cosmetic Act (hereafter "FDCA"), 21 U.S.C. § 301, *et. seq.*, and brought an in rem forfeiture action against the Defendant Articles and their contents pursuant to 21 U.S.C. § 334. (Docket No. 1, at ¶¶ 1-2). Both the Government and Hi-Tech agree that the Defendant Articles are considered a "food" within the meaning of the FDCA, 21 U.S.C. § 321 (ff). (Docket No. 1, at ¶ 5);(Docket No. 4, at ¶ 5). The Government contends that the Defendant Articles are "adulterated while held for sale after shipment of one or more of its ingredients in interstate commerce," as defined in the Act at 21 U.S.C. § 342(f)(1)(A), and as a result, present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling or, if the labeling does not discuss it, under ordinary conditions of use. (Docket No. 1, at ¶ 6). The Government further alleges that the Defendant Articles were held illegally within this Court's jurisdiction, and were subject to seizure and condemnation pursuant to 21 U.S.C. § 334. (Docket No.1, at ¶ 7).

On January 18, 2006, Hi-Tech claimed an interest in the above captioned property. (Docket No. 3). In its Third-Party Complaint, Hi-Tech seeks declaratory and injunctive relief with respect to the FDA Final Rule declaring dietary supplements containing ephedrine alkaloids to be adulterated. (Docket No. 4, at ¶3). Specifically, Hi-Tech alleges in its third party complaint that the Government "failed to meet their burden of proof to establish that dietary

supplements containing ephedrine alkaloids present an unreasonable risk under the FDCA, as amended by the DSHEA, 21 U.S.C. § 342(f)(1)(A)." *Id.* Hi-Tech claims the Final Rule was issued in violation of the Administrative Procedures Act (hereafter the "APA"), 5 U.S.C. § 706. *Id.* Further, Hi-Tech alleges that the Government violated Hi-Tech's due process rights under the Due Process Clause of the Fifth Amendment of the United States Constitution, and constituted a taking under the Fifth Amendment to the Constitution. *Id.*

Pursuant to a scheduling order issued on May 20, 2006 by the Honorable Thomas Hardiman, this Court established a schedule for filing summary judgment motions, responses and replies. The Government filed its motion for summary judgment, (Docket No. 34), and documents in support thereof on August 4, 2006. Hi-Tech then filed its motion for summary judgment, (Docket No. 44), and related documents on September 12, 2006. The parties subsequently filed both response and reply briefs.

On September 1, 2006, the parties jointly filed a notice of the outcome of the decision in the case of *Nutraceutical Corp.*, 459 F.3d 1033. (Docket No. 40). On March 21, 2007, the Government also notified this Court of the decision in the case of *Nutraceutical Corp. v. Von Eschenbach*, 2007 WL 779194 (D. Utah). (Docket No. 57). On June 12, 2007, this Court[6] ordered the parties to file a notice with the Court concerning any changes in the law as set forth in their respective motions for summary judgment, especially as they might pertain to the impact of the decisions issued in the two aforementioned *Nutraceutical* cases. (Docket No. 58). On June 29, 2007, Hi-Tech and the Government complied with this Court's order and filed the required notices pertaining to, *inter alia*, the *Nutraceutical* decisions. (Docket Nos. 59, 60).

[6] On April 9, 2007, this case was reassigned to the Honorable Nora Barry Fischer, following the elevation of the prior presiding judge, the Honorable Thomas Hardiman, to the Third Circuit Court of Appeals.

Moreover, on August 18, 2007, the Government filed a notice with this Court reporting a judgment and order in a case in the United States District Court for the Northern District of Georgia, *Hi-Tech Pharm., Inc., v. Crawford, et. al.*, 2007 WL 2345248. (Docket No. 61).

IV. DISCUSSION

A. Hi-Tech's Motion for Summary Judgment

In its motion for summary judgment Hi-Tech asserts that the following are at issue:

(1) "[W]hether the Defendant Articles are adulterated under 21 U.S.C. § 342(f)(1)(A) because they present an unreasonable risk of illness or injury under their labeled conditions of use;"

(2) whether the Final Rule was lawfully promulgated under the Administrative Procedures Act (APA) and its statutory authority;

(3) whether the Final Rule violates the requirements of the APA;

(4) whether the Final Rule violates DSHEA; and

(5) whether regardless of its validity, the Final Rule operates as law in these proceedings.[7] (Docket No. 44, at 5 - 6).

Hi-Tech also argues that: (1) the Final Rule violates DSHEA by employing a risk/benefit test to show adulteration, (Docket No. 44, at 10, 12); (2) that the Final Rule violates DSHEA's requirement that adulteration be proven under labeled conditions of use, (Docket No. 44, at 24); and (3) the FDA Final Rule is arbitrary and capricious, (Docket No. 44, at 28). The Court notes

[7] The Court notes that the majority of the issues that Hi-Tech raises pertain in one form or another to the Final Rule. The Court further notes that, as mentioned in the "Legal Standard" section, *supra*, a number of facts provided by the Government pertaining to the Final Rule, which could have been construed against Hi-Tech, were accepted by the Court based upon Hi-Tech's failure to provide its own concise statement of material facts in accordance with Local Rule 56.1.

that the first issue presented by Hi-Tech, whether the Defendant Articles are adulterated, is the same, and in fact the only, issue presented by the Government in its motion for summary judgment, and as such will be addressed under section "B" *infra*, pertaining to the Government's motion for summary judgment.

This Court finds that these were the identical issues presented in the well-reasoned and persuasive decision in *Hi-Tech*, 2007 WL 2345248. As noted *supra*, this Court has also considered the well-reasoned and persuasive decision in *Nutraceutical Corp.*, 459 F.3d 1033, an analogous case, in which the Tenth Circuit performed an in-depth analysis of the FDA Final Rule and held that the FDA properly conducted a risk benefit analysis under DSHEA in determining that EDS was unsafe at any level. The *Nutraceutical* Court further held that the FDA's determination that there is no dosage level of ephedrine dietary supplements that was acceptable was not arbitrary and capricious. *Nutraceutical Corp*, 459 F.3d at 1043. Furthermore, this Court considered a case within its own circuit, *NVE*, 436 F.3d 182, which involved a challenge by NVE Incorporated, a former manufacturer and distributor of EDS, to the FDA's determination that EDS was adulterated food under the DSHEA. The issues addressed in the *NVE* case were different from the issues presented in the instant matter; however, the *NVE* Court provided guidance to other courts reviewing cases involving the Final Rule when it held, *inter alia*, that the FDA's factual determinations and legal conclusions are entitled to deference under the APA in a case involving the FDA's regulation banning EDS supplements.

In banning EDS, the FDA concluded that the risks posed by EDS outweighed the benefits after a highly extensive review of the scientific evidence before it. *Hi-Tech Pharm*, 2007 WL 2345248, at *12. The review of scientific literature is properly within the province and authority of the FDA. Therefore, the courts grant deference to the FDA's findings based on its expertise.

Nutraceutical, 459 F.3d at 1043; *see also Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653-54 (1973) (finding that the FDA is "peculiarly suited" to evaluate scientific reports, a matter "not...well left to a court without chemical or medical background" because it "necessarily implicates complex chemical and pharmacological considerations"); *see also NVE*, 436 F.3d at 186 (holding that the FDA's factual and legal determinations in its rule banning ephedrine alkaloids are entitled to deference under the Administrative Procedure Act, and that judicial review is limited to the administrative record); *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001); *United States v. Algon Chem. Inc.*, 879 F.2d 1154, 1159 (3d Cir. 1989).

Having considered the *Hi-Tech, Nutraceutical,* and *NVE* cases, and having conducted its own research and analysis, this Court will not re-invent the findings and analysis in the above-cited cases, with which it agrees. Accordingly, this Court finds the following based upon its review of Hi-Tech's and the Government's filings, its own research and analysis, and consideration of the opinions reached in the *Hi-Tech, Nutraceutical,* and *NVE* cases:

(1) the FDA was required by Congress, under the DSHEA, to conduct a risk-benefit analysis, and the FDA properly did this, *Nutraceutical*, 459 F.3d at 1038;

(2) the FDA reasonably concluded that there is no level of EDS that is reasonably safe, therefore, the FDA met its statutory burden for justifying a total ban of EDS by a preponderance of the evidence, *Id.* at 1043;

(3) the FDA complied with the requirements of both the APA and the DSHEA, and the FDA Final Rule is a logical result of the earlier proposed rule pertaining to EDS regulation, *Hi-Tech,* 2007 WL 2345248 at *7;

(4) the risk-benefit analysis employed by the FDA to determine if EDS products were adulterated is an interpretive versus a substantive rule, and therefore the FDA did not have "to

abide by the APA's notice and comment requirements in utilizing the [risk-benefit] analysis," *Id.* at *8;

(5) the FDA's interpretation of "unreasonable risk" in DSHEA is an interpretive rule and thus the FDA was not required to allow time for notice and comment for its utilization of a risk-benefit analysis, *Id.* at *9;

(6) the FDA fulfilled its burden of proof and showed "by a preponderance of the evidence that dietary supplements containing any dosage of ephedrine alkaloids present a significant or unreasonable risk of illness or injury," thus defeating Hi-Tech's argument that the Final Rule violates the DSHEA's requirement that adulteration be proven under labeled conditions of use, *Id.* at *11;

(7) the FDA did not act in an arbitrary and capricious manner when enacting the Final Rule, *Id.* at *12; *see also Nutraceutical*, 459 F.3d at 1043 ("The FDA was not arbitrary or capricious in its Final Rule"); and

(8) where the Government proceeds in a forfeiture action alleging a dietary supplement to be adulterated and has the support of a valid regulation declaring the questioned supplement to be adulterated, "the court must defer to the agency's regulation and should not review anew the question of adulteration,"[8] *Hi-Tech Pharm.*, 2007 WL 2345248 at *14.

Accordingly, the Court DENIES Hi-Tech's motion for summary judgment [DE 45].

[8] As noted above, Hi-Tech argues that the Final Rule does not function as law in the present proceeding. (Docket No. 44, at 6). The Government alleges in its notice to the Court advising of any changes to case law that the Final Rule has the force and effect of law, (Docket No. 60, at 8), and that the Tenth Circuit's *Nutraceutical* decision provides indirect support for this proposition. *Id.*, at n.7; *see* Government's Opposition and Reply Memo at Dockent No. 51, *see also Nutraceutical*, 459 F.3d at 1037 (quoting *NVE*, 436 F.3d at 194, 196) (noting that courts owe deference to an agency's interpretation of the statute and regulations it administers and that regulations that are validly promulgated under the federal FDCA normally have the force of law in enforcement proceedings) (internal citations omitted)). This identical issue was addressed in the *Hi-Tech* case, which also cited to the *NVE* and *Nutraceutical* cases.

B. Government's Motion for Summary Judgment

The Government maintains that the only issue presented on summary judgment is "whether the seized articles are adulterated under 21 U.S.C. § 342(f)(1)(A) because they present an unreasonable risk of illness or injury under their labeled conditions of use." (Docket No. 35, at 4). The Defendant acknowledges that this is the sole issue advanced by the Government. (Docket No. 44, at 5). The Court again notes that this was the identical issue raised by the Government in the *Hi-Tech* and *Nutraceutical* cases. As the Court stated previously, it is persuaded by the well-reasoned opinions in the *Hi-Tech* and *Nutraceutical* cases, and this Court will not re-iterate the analysis of those courts in the instant opinion. Rather this Court finds, given its review of Hi-Tech's and the Government's filings before this Court, the Court's own research and analysis, and its consideration of the opinions of *Hi-Tech* and *Nutraceutical*, that the seized Defendant Articles are adulterated pursuant to 21 U.S.C. § 342(f)(1)(A) because they present an unreasonable risk of illness or injury under their labeled conditions of use and are therefore subject to seizure under 21 U.S.C. § 334.[9]

[9] As in the *Hi-Tech* case, this Court finds that regardless of whether 21 U.S.C. § 342(f) requires the adulteration issue to be decided *de novo*, EDS are properly considered adulterated under the DSHEA, as the FDA established by a preponderance of the evidence that any dosage of EDS presents a significant or unreasonable risk of illness or injury. *Hi-Tech,* 2007 WL 2345248, at *11.

Products containing EDS often contain other stimulants, such as caffeine, which may have synergistic effects and increase the potential for adverse effects. These products, like other sympathomimetics, raise blood pressure, increase heart rate, and otherwise stress the circulatory system. 69 Fed. Reg. at 6789;*see also U.S. FDA request seizure of more dietary supplement containing ephedrine alkaloids*, PATIENT CARE WEEKLY, April 2, 2006, at 9. Ephedra can cause irregular heartbeat, anxiety, tremors, sleeplessness, headache, seizures, heart attack, and stroke. Symposium, *Health Care in America: A New Generation of Challenges*, 17 STAN. L. & POL'Y REV. 165, 182 n.58 (2006)(internal citations omitted). Scientific evidence and numerous reports of adverse effects, including death, occurring after consumption of these supplements containing EDS, has raised questions about their safety. 69 Fed. Reg. at 6789. For instance, in 1996, a 20-year old college student died after consuming a product containing ephedra. *Health Care in America: A New Generation of Challenges*, *supra*, at 182 n.58. As another example, In 1999, a 21-year old man died during exercise after consuming an ephedra product. *Id.* In March 2003, before the Final Rule was announced, the FDA "indicated it was considering 'stronger action against ephedra' and invited comments" from various manufacturers, health professionals, and the public "to help the agency determine ephedra's relative safety" and whether EDS presents a unreasonable or significant risk of illness or injury. Kenneth R. Pyle, *Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products*, 61 FOOD & DRUG L.J. 701, 704 (2006) (quoting the language of the DSHEA). The premature death of 23-year old Steve Bechler, a

Accordingly, the court finds that no genuine issue of material fact exists for trial, and hereby GRANTS the Government's motion for summary judgment [DE 34].

V. CONCLUSION

Accordingly, upon due consideration of the following:

1) the Government's motion for summary judgment, related briefs, statement of facts, and appendix (Docket Nos. 34, 35, and 36); 2) Hi-Tech's motion in opposition to the Government's motion for summary judgment and related brief (Docket Nos. 43 and 44); 3) Hi-Tech's motion for summary judgment and related briefs (Docket Nos. 45, 46 and 56); 4) the Government's reply in opposition to Hi-Tech's motion for summary judgment and in support of the Government's motion for summary judgment (Docket No. 52); 5) Hi-Tech's notice to the Court regarding the effect of the *Nutraceutical* decision on the instant case (Docket No. 59); 6) the Government's notice to the Court advising of any changes to case law concerning issues in the pending summary judgement motions (Docket No. 60); and 7) the Government's notice of the decision in the *Hi-Tech Pharm., Inc., v. Crawford* case from the Northern District of Georgia (Docket No. 61), as well as the Court's consideration of the decisions in the Tenth Circuit case

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Baltimore Orioles pitcher, likely influenced the FDA's renewed efforts in March 2003 "to not only regulate ephedra, but to declare it adulterated and remove it from the marketplace." Pyle *supra*, at 705. Furthermore, a search of the internet reveals that lawsuits against makers of ephedra products are commonplace. For example, Rhea McAllister was awarded $2.4 million in actual damages and $5 million in punitive damages after suffering brain damage from a stroke after taking Metabolife, a diet-supplement that contained ephedra. *Jury awards $7.4 million in ephedra lawsuit; Woman suffered brain damage after taking Metabolife supplement*, Available at www.msnbc.msn.com/id/5288323, last visited October 15, 2007. Additionally, several of Muscletech Research and Development, Inc.'s consumers suffered severe injuries, including heart attacks and strokes and eventually more than thirty civil actions for personal injuries and wrongful deaths allegedly caused by ephedra were filed in federal and state courts in the United States. *In re RSM Richter Inc. v. Aguilar (In Re Ephedra Prods. Liab. Litig.)*, 349 B.R. 333 (D.N.Y. 2006); *see also In re Ephedra Prods. Liab. Litig.*, 393 F.Supp. 2d 181 (S.D.N.Y. 2005) (the consolidated action of numerous civil actions claiming personal injury or wrongful death caused by dietary supplements containing ephedra).

of *Hi-Tech Pharm., Inc., v. Crawford*, *Nutraceutical Corp. v. Von Eschenbach*, and *NVE Inc. v. HHS* cases, IT IS HEREBY ORDERED that:

1) The Government's motion for summary judgment [DE 34] is GRANTED; and

2) Hi-Tech's motion for summary judgment [DE 45] is DENIED.

An appropriate order follows.

Nora Barry Fischer
United States District Judge

cc: all counsel of record

Date: October 15, 2007